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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

KAUSHAL, SUMESH

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 01/29/2003

20

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/442,542

Applicant(s)

SHEA ET AL.

Examiner

Sumesh Kaushal Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-68,102 and 103 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 54-65 is/are allowed.
- 6) ☐ Claim(s) 1-13,17-25,35-37,40-68,102 and 103 is/are rejected.
- 7) ☐ Claim(s) 14-16,26-34,38 and 39 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 15.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### DETAILED ACTION

Applicant's response filed on 11/04/02 has been acknowledged.

*Claims 1, 13, 48, 66 and 68 are amended.*

*Claims 1-68 and 102-103 are pending and were examined in this office action.*

► *If the claims are amended, added and/or canceled in response to this office action the applicants are required to follow Amendment Practice under 37 CFR § 1.121 (<http://www.uspto.gov>) and A CLEAN COPY OF ALL PENDING CLAIMS IS REQUESTED.*

Applicant's arguments filed 11/04/02 have been fully considered but they are found not persuasive for new grounds of rejection below.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The scope of invention as claimed encompasses a product-by-process, wherein the invention as claimed fail to recite any structural limitation that distinguishes the claimed product over the prior art of record. Given the broadest reasonable interpretation the composition as

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claimed merely reads upon *a porous gel containing a nucleic acid segment*, which has been clearly anticipated by the cited art of record. Incorporation of specific structural limitations that distinguishes the product over the prior art would obviate the instant rejection.

Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps (see MPEP §2113). Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)

Claim 1-13, 17-25, 35-37, 40-68, 102 and 103 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Wheatley et al (US 4933185, 1990, *ref. of record*). The cited art teaches a composition for controlled release of a biologically active substance comprising a microcapsules consisting of alginate matrix. The cited art further teaches a method of controlling the porosity of the microcapsules by setting the molecular weight of the cross-linked polymer, its concentration and duration of gelling reaction (col.1 lines 45-60, col.4, line 60-64; col.5, lines 40-55). The cited art further teaches a composition that comprises both permeable and impermeable polymer structures within the same microcapsules (col.5, lines 55-68). For example, the cited art teaches that the core of a microcapsule is formed of an ionically cross-linked polysaccharide calcium alginate, which is further coated with poly-cationic skin of poly-L-lysine (abstract). The cited art teaches that core polymer and the membrane have different

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permeability (col.6 line 13-37). In addition the cited art further teaches that the biologically active substances are selected from the group consisting of proteins, nucleic acid, viruses and inorganic compounds (col.4, line 44-68; col. 6, line 50-64; col.7, line 48-51, clo.8, line 17-25). Thus considering the lack of specific structural limitations in the invention as claimed and given the broadest reasonable interpretation the cited art clearly anticipate the invention as claimed.

### ***Conclusion***

Claims 1-13, 17-25, 35-37, 40-68, 102 and 103 are rejected.

Claims 54-65 are allowable

Claims 14-16, 26-34, 38 and 39 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten independent form including all of the limitation of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal Ph.D. whose telephone number is 703-305-6838. The examiner can normally be reached on Mon-Fri. from 9AM-5PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yucel Irem Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-8724 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

*S. Kaushal*  
**Patent examiner**



**JEFFREY FREDMAN**  
**PRIMARY EXAMINER**